

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Offic**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/072,994 05/05/98 COTTAREL

G MIV-032.02

025181  
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BOSTON MA 02109

HM22/0509

EXAMINER

PAK, M	ART UNIT	PAPER NUMBER
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1646

23

DATE MAILED:

05/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/072,994</b>	Applicant(s) <b>Cottarel et al.</b>
	Examiner <b>Michael Pak</b>	Art Unit <b>1646</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on Feb 16, 2001
- 2a)  This action is FINAL.                            2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) 1-13 and 23-36 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 14-22 and 37-40 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15) <input type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>20</u>	20) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed 16 February 2001 (Paper No. 22) has been entered.
  
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
  
3. Applicant's arguments filed 16 February 2001 (Paper No. 22) have been fully considered but they are not found persuasive.
  
4. This application contains claims 1-13 and 23-36 drawn to an invention non-elected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) MEP. § 821.01.

***Information Disclosure Statement***

5. The information disclosure statement filed 2 February 2001 (Paper No. 20) fails to comply in part with the provisions of 37 CFR 1.97, 1.98 and MEP. § 609 because reference BX is a search report without a publication date, author, and citation. The search report has been placed in the application file, but the information referred to therein has not been considered as to the

Serial Number: 09/072,994  
Art Unit 1646

2

merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MEP. § 609 ¶ C(1).

***Claim Rejections - 35 USC § 101***

6. Claims 14-22 and 37-40 remains rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The reasons for the rejection has been set forth in the previous office action.

Applicants argue that the application points out on pages 9 and 25 of the specification that the nucleic acids of the invention can be used in diagnostic assays for detecting the presence of a Candida pathogen in a patient sample by means of a PCR based procedure. However, the asserted utility in the specification is directed to a general utility and not a specific utility. The diagnostic assay can be performed with any Candida nucleic acid sequence and the claimed nucleic acid has the general characteristic of a Candida nucleic acid. The references

cited are not directed to CAK kinase but general references about Candida diagnostics and infections.

Applicants argue that the specification on page 22 teaches that CAK kinase can be used to prepare anti-fungal compositions by generating dominant-negative mutants and subfragments of CAK. However, the specification on page 22 discusses generically of TYP1 or CDK and not the CAK specifically. Furthermore, CAK1 is an orphan kinase whose substrate activity or function is not known. The closest structural identities are to many different kinases at approximately 25% sequence identity. The claimed polypeptides do not substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its function and use. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed. The references cited are not directed to CAK kinase but general references about Candida antifungal agents.

Applicants argue that reference of Whiteway et al. Found that unaltered Candida Albican genes interfered with a Sacharmomyces Cerevisiae signal transduction pathway involving the homologs of those Candida genes. However, the Whiteway et

al. do not use the CAK kinase and further experimentation is needed to determine the function of the CAK kinase.

Claims 14-22 and 37-40 remains rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112***

7. Claims 37-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 37 recite a newly amended limitation of ~~☒~~stringent conditions of 2.0 x SSC at 50°C~~☒~~ which is new matter because the specification on page 13 does not disclose the subgeneric invention of the newly amended limitation. The specification discloses the specific hybridization and wash conditions.

8. Claims 37-40 are rejected under 35 U.S.C. § 112, second

paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is indefinite for recitation of a newly amended limitation of ~~stringent conditions of 2.0 x SSC at 50°C~~ which is not clear because the specification on page 13 discusses hybridization and washing whereas the claim limitation is directed to stringent conditions. Since the results of stringent hybridization condition is in melting temperature which is a statistical analysis of binding at 50% duplex formation between DNA strands. Thus, at a given T<sub>m</sub> there is always 50% duplex formation, thus it is not clear how one skilled in the art distinguishes what hybridizes and not hybridizes at stringent hybridization conditions. Claims 38-40 are dependent on claim 37.

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MEP. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this

Serial Number: 09/072,994  
Art Unit 1646

6

action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Michael D. Pak*

Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
4 May 2001